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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/449,924 12/02/99 SAINT-LEGER

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EXAMINER

HM22/0620

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ARLINGTON VA 22201

PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/449,924

Applicant(s)

SAINT-LEGER, DIDIER

Examiner

Amy E Pulliam

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the Request for Two Months Extension of Time and the Request under 37 C.F.R. 1.114, both received April 27, 2001.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2001 has been entered.

Applicant applied for a continued prosecution application on May 4, 2001. However, because applicant already filed for continued examination under 37 CFR 1.114, the request for a CPA was not entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/24329 to Blieszner *et al* (hereinafter WO '329). WO '329

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discloses a personal care composition which includes water, dimethicone, a polymeric emulsifier, a water soluble polyol, a pH adjusting agent, an anti-microbial agent, and a chelating agent. WO '329 further discloses that the preferred antimicrobial agent includes 3-iodo-2-propynyl butyl carbamate (p 5, paragraph 2), and that the polyol may be chosen from a group including 1,2,4-butane triol, 1,2,6-hexane triol, and sorbitol (p 11, paragraph 4). Further, in the examples, WO '329 teaches that the polyol and the antimicrobial agent are present in amounts that fall within the range claimed by applicant. In addition, WO '439 teaches that additives, such as fragrances, skin smoothing aids, moisteners, humectants, emollients, powders (p 14, paragraph 2), silicone oils, and organic base pH adjusting agents can also be included (p 20, example a). Lastly, although the preferred embodiment of the composition disclosed by WO '329 is a wipe, they also teach that the composition may be administered through spraying, dripping, smoothing, massaging, or rubbing. It is the position of the examiner that this disclosure is broader than simply a wipe, and allows for other forms of application, and therefore it reads on the limitations of applicant's claim 12.

Applicant's arguments have been fully considered but are not found persuasive. Applicant has amended the claims to consisting essentially of language. However, applicant's argument based on the change of claim language from comprising to consisting essentially of is not persuasive. A finding that one of the antimicrobial agents is sufficient to produce an antimicrobial effect is not patentable. From the very fact that the prior art states clearly that 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 3-iodo-2-propynyl butyl carbamate are both antimicrobial agents, this shows that they

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each possess a certain degree of antimicrobial activity. It is within the skill of the art that one would use a combination of agents having the same function to obtain either an additive or a synergistic effect. Furthermore, in applicant's specification, page 5, lines 18-26, it states that the composition can also contain other anti-bacterial or anti-fungal agents, such as selenium sulphide. Applicant himself teaches that the composition can contain a mixture of agents. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12 and 22 above. WO '329 does not teach the exact polyol claimed in claim 5. However, applicant teaches that many polyols can be used in the formulation and achieve the same effect. Further, WO' 329 does teach the inclusion of some of the polyols claimed by applicant in claim 4. Therefore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any polyol in the formulation disclosed by WO '329, with the expected results being an equally successful antimicrobial composition. Therefore the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention

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was made. The burden is shifted to applicant to disclose the criticality in the specific compound claimed in claim 5 of the instant application.

Applicant's arguments have been fully considered but are not found persuasive. This rejection is maintained for the reasons stated above.

Claims 1-13 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12, and 22 above, and further in view of US Patent 5,552,425 to Merianos (hereinafter US '425). WO '329 teaches that the composition can be used to clean and disinfect the skin, but does not teach its use as a shampoo. US '425 discloses an antimicrobial composition which comprises 3-iodo-2-propynyl butyl carbamate, as well as a glycol (abstract). US '425 further teaches that their composition can be used as a shampoo (c 36, claim 8). It is the position of the examiner that one of ordinary skill in the art would have been motivated to use the composition disclosed by WO '329 as a shampoo composition, in addition to a skin composition. The composition disclosed by WO '329 must be sensitive to the skin in order to be useful as a skin formulation, and therefore would not be harmful if applied to the scalp. Further, based on the disclosure of US '425, the active ingredient (IPBC) is acceptable in shampoo formulations. One of ordinary skill in the art would have expected a shampoo composition with the same antimicrobial properties achieved by the skin formulation. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Applicant's arguments have been fully considered but are not found persuasive.
This rejection is maintained for the reasons stated above.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

AEP
June 18, 2001


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600